Overal 10.2.e, tenzij anders aangegeven.

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Doc. 223

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative Information

Recipient (Name of NCA) Dutch Healthcare Inspectorate	Stamp box
Address of National Competent Authority St. Jacobsstraat 16 NL - 3511 BS Utrecht	

Date of this report

2017-[redacted]

Reference number assigned by the manufacturer

[redacted]

Reference number assigned by NCA

[redacted]

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ◉ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ◉ no

Classification of Incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent

United States FDA

2 Information on submitter of the report

Status of submitter

- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (Identify the role)

3 Manufacturer information

new

Name Cyberonics Inc.	
Contact Name [redacted]	
Address 100 Cyberonics Boulevard	
Postcode 77058	**City** Houston
Phone +1(866)[redacted]	**Fax**
E-mail clinicaltechnicalservices@livanova.com	**Country** US - USA

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** AT - Austria

5 Submitter's information

new

Name Cyberonics Inc.	
Contact Name [redacted]	
Address 100 Cyberonics Boulevard	
Postcode 77058	**City** Houston
Phone +1(866)[redacted]	**Fax**
E-mail clinicaltechnicalservices@livanova.com	**Country** US - USA

6 Medical device information

Doc. 223
Rev.

Class

- (•) AIMD Active implants
- ( ) MDD Class III
- ( ) MDD Class IIb
- ( ) MDD Class IIa
- ( ) MDD Class I
- ( ) IVD Annex II List A
- ( ) IVD Annex II List B
- ( ) IVD Devices for self-testing
- ( ) IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	44041
Nomenclature text	
Vagus nerve electrical stimulation system lead	
Commercial name/ brand name / make	
Lead Model Unknown	
Model number	**Catalogue number**
Unknown	NA
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**
Unknown	Unknown
Software version number (if applicable)	
NA	
Device Mfr Date	**Expiry date**
Implant date (For implants only)	**Explant date (For implants only)**
Duration of implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Unknown	
Accessories / associated devices (if applicable)	
Generator Model 102 SN [redacted] & Generator Model 103 SN [redacted]	
Notified Body (NB) ID-number	
0344	

7 Incident information

Date the incident occurred
[redacted]
Incident description narrative
[redacted]
User facility report reference number, if applicable
Manufacturer's awareness date
2013-[redacted]

Number of patients involved (If known)	**Number of medical devices involved (if known)**
1	1.
Medical device current location/disposition (if known)	
The lead was reportedly discarded after surgery.	

24 lid 4 +
25 lid 3 +
10.1.d +
10.2.d +
10.2.g

Operator of the medical device at the time of incident (select one)

- ○ Healthcare Professional
- ◉ Patient
- ○ Other

Usage of the medical device (select from list below)

- ◉ initial use
- ○ reuse of a single use medical device
- ○ reuse of a reusable medical device
- ○ re-serviced/refurbished
- ○ other
- ○ problem noted prior use

8 Patient information

Patient outcome

The patient [redacted]

24 lid 4 + 25 lid 3 + 10.1.d + 10.2.d + 10.2.g

Remedial action taken by the healthcare facility relevant to the care of the patient

The healthcare facility opted to replace the patient's lead to resolve the high impedance.

Gender, if applicable

[redacted]

Age of the patient at the time of incident, if applicable

[redacted]

units

◉ Years ○ months ○ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

[redacted]

Contact person within the facility

Dr. [redacted]

Address

[redacted]

Postcode

[redacted]

City

[redacted]

Phone

Fax

E-mail

[redacted]

Country

NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)
Manufacturer's preliminary analysis
Initial corrective actions/preventive actions implemented by the manufacturer
Expected date of next report

11 Results of manufacturers final investigation (Final report)
The manufacturer's device analysis results The device was not returned to the manufacturer so an analysis could not be performed.
Remedial action/corrective action/preventive action / Field Safety Corrective Action N/A
Time schedule for the implementation of the identified actions
Final comments from the manufacturer [redacted] The lead was discarded after explant, so was unable to be analyzed by the manufacturer.
Further investigations
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause? (●) Yes ( ) No
Number of similar incidents 76
If yes, state in which countries and the report reference numbers of the incidents. Austria (AT) - 1 Belgium (BE) - 4 Czech Republic (CZ) - 1 France (FR) - 7 Germany (DE) - 5 Greece (GR) - 1 Ireland (IE) - 1

24 lid 4 +
25 lid 3 +
10.1.d +
10.2.d +
10.2.g

Israel (IL) - 4
Italy (IT) - 4
Norway (NO) - 2
Saudi Arabia (SA) - 2
Spain (ES) - 5
Sweden (SE) - 12
The Netherlands (NL) - 6
Turkey (TR) - 6
Great Britain (GB) - 15

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☒ IS	☒ IT	☒ LI	☐ LT	☒ LU	☐ LV	☐ MT	☒ NL
☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

print | check | send XML-data by E-Mail

I affirm that the information given above is correct to the best of my knowledge